PATENT
Attorney Docket No. 275.00090101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	David MUNN *et al.*	Group Art Unit:	1614
Application No.:	10/780,150	Confirmation No.:	1273
Filed:	February 17, 2004	Examiner:	Timothy P. Thomas

FOR: REGULATION OF T CELL-MEDIATED IMMUNITY BY D ISOMERS OF INHIBITORS OF INDOLEAMINE-2,3-DIOXYGENASE

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DECLARATION OF DR. GEORGE C. PRENDERGAST

I, George C. Prendergast, hereby declare that:

1. I am a President and CEO of the Lankenau Institute for Medical Research, located west of the city of Philadelphia, Pennsylvania. I hold a Ph.D. in Molecular Biology, received from Princeton University in 1989. My career as a cancer researcher includes training as an American Cancer Society Postdoctoral Fellow at the Howard Hughes Medical Institute at NYU Medical Center, working at the Department of Cancer Research at Merck Research Laboratories, appointment as Assistant Professor and later Associate Professor at the Wistar Institute, and experience as a Senior Director of the Cancer Research Group at the DuPont Pharmaceutical Company. I have published over 100 peer-reviewed research reports, and I am an inventor or co-inventor on 23 patents or patent applications. I am familiar with scientific progress and various developments in the field of cancer research. Therefore, I can be considered an expert in the field of cancer research.

2. The purpose of this Declaration is to provide factual evidence that 1-D-methyl-tryptophan (D-1MT) can be effective in inhibiting cancer growth in multiple cancer types.

3. Attached as Exhibits A and B are graphs presenting data, which demonstrate the anti-cancer effects of the administration of D-1MT in conjunction with a chemotherapeutic agent in a treatment regimen against lung cancer and colon cancer, respectively.

4. The data presented in Exhibit A was obtained as follows. C57/Bl6 mice were injected with $1x10^6$ LLC1 lung tumor cells subcutaneously (SC) on day 1. On day 7, 400 mg/kg of D-1MT was administered perorally (PO) twice daily (BID) Monday through Friday throughout the length of the experiment. On days 9, 11, and 14, 125 mg/kg of cyclophosphamide (CTX) was injected intraperitoneally (IP). Tumor volume was measured on days 15, 18, and 22. As shown by the data in Exhibit A, the administration of D-1MT with CTX effectively inhibited lung cancer growth, and the effect was greater than the effect of either compound administered individually or the combined effect of the compounds administered individually.

5. The data presented in Exhibit B was obtained as follows. Balb/C mice were injected with $1x10^6$ CT26 colon tumor cells SC on day 0. On day 7, 400 mg/kg of D-1MT was administered PO twice daily (BID) Monday through Friday throughout the length of the experiment. On days 9 and 11, 125 mg/kg of CTX was injected IP. Tumor volume was measured on days 15, 18, and 22. As shown in the data presented in Exhibit B, the administration of D-1MT with CTX effectively inhibited colon cancer growth, and the effect was greater than the effect of either compound administered individually or the combined effect of the compounds administered individually.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made based on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-referenced application or any patent issued therefrom.

9/23/08
Date

George C. Prendergast, Ph.D.

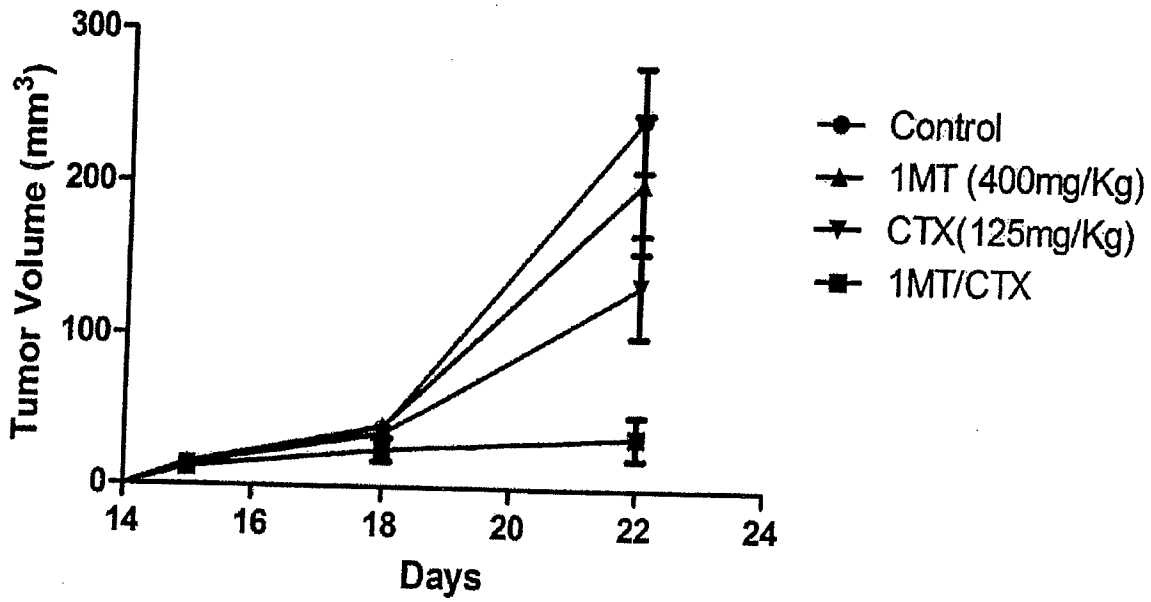
300
200
100
0
Tumor Volume (mm3)
14
16
18
20
22
24
Days
Control
1MT (400mg/Kg)
CTX(125mg/Kg)
1MT/CTX

Exhibit A

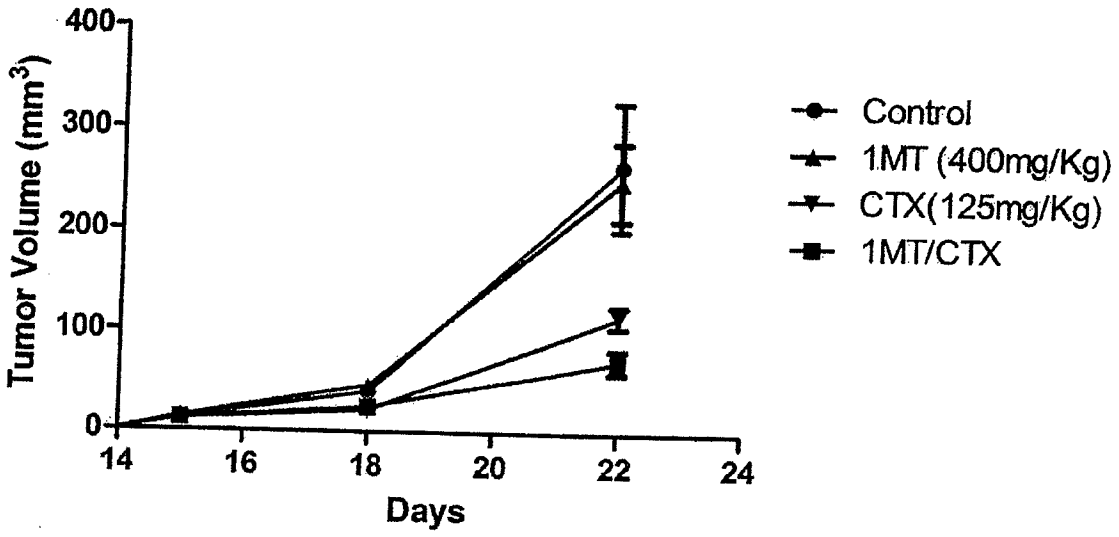
Tumor Volume (mm3)
400
300
200
100
0
14
16
18
20
22
24
Days
Control
1MT (400mg/Kg)
CTX(125mg/Kg)
1MT/CTX

Exhibit B